

Atty. Docket No. BMID 9941 US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Goerlach-Graw, *et al.*

Application No.: 09/594,972

Group No.: 1641

Filed: June 15, 2000

Examiner: Nguyen, Bao Thuy L

For: ELEMENT, METHOD AND KIT FOR THE DETERMINATION OF AN
ANALYTE IN A LIQUID

BRIEF OF GOERLACH-GRAW ET AL.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants appeal the Final Rejection dated April 20, 2005 of claims 15-26 of this application.

STATUS OF THE CLAIMS

The captioned application was filed as Serial No. 09/594,972 on June 15, 2000. The 14 claims in that initial filing were cancelled without prejudice or disclaimer of the subject matter claimed therein by Preliminary Amendment on November 21, 2000, and new claims 15-42 were added. Claims 15-42 were subjected to an election/restriction requirement: Group I – claims 15-26 drawn to an element for the determination of an analyte in a liquid; Group II – claims 27-31 drawn to a method for the determination of the presence of an analyte in a sample; Group III – claims 32-41 drawn to an element for the determination of an analyte in a sample; and Group IV – claim 42 drawn to a kit for determining an analyte. Group I, claims 15-26 were provisionally elected for prosecution, with traverse. Claims 27-42 were withdrawn from consideration and subsequently cancelled.

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Claims 15-26 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Claims 15-26 further stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

SUMMARY OF THE INVENTION

The present invention relates to an element for the determination of an analyte by a specific binding reaction of two bioaffine binding partners (page 4 lines 18-20). The element enables liquid transport between a sample application zone and a detection zone downstream thereof as well as a zone containing immobilized analyte or analyte analogue between the sample application and detection zones (page 5 lines 16-22 and page 7 line 30 – page 8 line 2). A conjugate impregnated in a matrix material is located upstream of the zone containing immobilized analyte or analyte analogue that can be detached by liquid from the matrix material and includes a bioaffine binding partner 1 capable of a specific binding reaction with the analyte and a low molecular organic molecule detectable label (page 9 line 15 to page 10 line 4 and lines 29-33). A universal conjugate is upstream of the zone containing immobilized analyte or analyte analogue which can also be detached by liquid and is composed of a bioaffine binding partner 2 capable of a specific binding reaction with the detectable label 1 and a visually detectable label (page 10 lines 6-25). The visually detectable label is a direct visually detectable label formed to carry out the determination of the analyte in the detection zone (page 10 lines 29-33).

ISSUES

The issues on appeal are whether or not the pending claims fail to comply with the written description requirement and whether or not the pending claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

GROUPING OF CLAIMS

Claims 15-26 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

Claims 15-26 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

ARGUMENT

Claims 15-26 stand rejected under 35 U.S.C. 112, first paragraph. Claims 16-26 depend from claim 15.

The Examiner has asserted that nowhere in the specification is there a specific recitation that the detection zone is the last zone that allows liquid transport, nor is there a specific recitation that the detection zone is devoid of a binding reagent.

The written description requirement is separate from the enablement requirement of 35 U.S.C. 112; it is not necessary that the claimed subject matter be described identically but that the originally filed disclosure convey to those skilled in the art that appellant had invented the subject matter now claimed. Precisely how close the original description must come to comply with the description requirement must be determined on a case by case basis as a question of fact. *In re Barker*, 194 USPQ 470 (CCPA 1977), *cert. den.*, *sub. nom.*, *Barker v. Parker*, 197 USPQ 271 (1978); *In re Wilder*, 222 USPQ 369 (Fed. Cir. 1984), *cert den.*, *sub. nom.*; *Wilder v. Mossinghoff*, 105 S. Ct. 1173 (1985).

Turning first to the issue regarding claim 15, as to an adequate written description for the claimed detection zone “being the last zone of the element that allows liquid transport”, it is submitted that the Examiner did not provide a reasonable basis for finding no support

for the claimed detection zone being the last zone of the element that allows liquid transport.

It is clear from each of the Figures 1-4, supported by the text of the specification that there are four matrix zones located on a support material that is itself not permeable to liquid. In describing Figure 1, the specification teaches “a liquid transport path which leads from the sample application zone (1) through the conjugate zone (2) . . . and the capture zone (3) . . . into the detection zone (4). (Column 14 lines 26-31). It is noted that Figure 1 illustrates only four zones (1-4) on the liquid impermeable support (5). An artisan would readily appreciate that the detection zone (4) of the Figures is the last zone of the element that allows liquid transport.

This same liquid transport path – with the detection zone being the last zone of the element that allows liquid transport - is taught with regards to Figures 2-4. Specific to Figure 2, it is taught that, “sample is firstly applied to the sample application zone (1). Subsequently sufficient elution agent is applied to the elution agent application zone (6) that analyte is transported into the conjugate zone (2) . . . and the complex that is formed reaches the detection zone (4) via zone (3)”. (Pages 15 last line to Page 16 line 8). It is noted that the sequence of zones (1-4) is the same for Figures 1-2, and 4. (Page 16 lines 15-16). Figure 3 interchanges the sample application zone (1) and the conjugate zone (2), but also teaches the detection zone (4) as being the last matrix zone. (Column 16 lines 15-21). Again, it is noted that in each of the embodiments (Figures 1-4), the detection zone 4 is the last zone of the element that allows liquid transport.

Moreover, the specification is replete with descriptions that the liquid sample and/or a mixture of liquid sample and elution liquid moves toward the detection zone – the last zone on the support. In that regard, attention is directed to page 10 lines 32-33 where it is taught, “they can be detached by liquid and transported towards the detection zone”. Further, at page 12 lines 32-34, it teaches “in order to transport the constituents of the sample, especially the analyte which may be present, with liquid towards the detection zone.” Page 13 lines 3-5 of the specification teaches, “This detection complex is

transported with the liquid into the detection zone and is determined there”. Page 13 lines 5-12 of the specification teaches, “Only if analyte was present in the sample does visually detectable label 2 reach the detection zone in the form of the previously mentioned complex and can be detected there. If no analyte was present . . . the mixture of conjugates 1 and 2 is bound . . . and no visually detectable label 2 reaches the detection zone”. Still further, at page 13 lines 25-27, “If it is intended to transport the sample through the element . . . into the detection zone using an additional elution agent, a kit . . .” Page 14 lines 7-9 teaches that, “elution agent is taken up via the elution agent application zone and migrates through the various zones into the detection zone.”

An “explicit” use of the claimed term “last zone” is not required under 35 U.S.C. 112, first paragraph. An invention claimed need only be described ipsis verbis in the specification in order to satisfy the disclosure requirements of 35 U.S.C. 112. Ex parte Holt, 19 USPQ2d 1211 (Bd Pat App & Inter, 1991).

It is submitted that the original description would have conveyed to the artisan that the inventors had possession of the subject matter they now claim at the time of filing the application. Accordingly, it is submitted that the Examiner had no reasonable basis for challenging the disclosure as to support for the detection zone being the last zone of the element that allows liquid transport.

With regard to claim 15, the Examiner states that there is no “specific recitation” in the specification for the claimed detection zone “devoid” of a binding reagent. The Examiner’s requirement of an “explicit” disclosure of the claimed features is not required by 35 U.S.C. 112, first paragraph. The Examiner did not provide a reasonable basis for finding no support for the claimed detection zone being devoid of binding reagent.

While the specification does not explicitly recite that the detection zone as “devoid” of a binding reagent as claimed, it certainly does provide implicit support with reasonable clarity. One specific example of support for the phrase “devoid of a binding reagent”, is found in an example at Page 24, last paragraph. That Example describes a fleece

Detection Zone (4) in detail, providing specifics on its composition as well as its absorptive capacity. This example describes a detection zone (4) and includes reference number (4), which is also used in each of the Figures 1-4. Importantly, this example of the detection zone (4) lacks a binding reagent. As such, there is implicit support in both the text of the specification, and by reference in each of the Figures of a detection zone, devoid of a binding reagent.

Still further, the specification makes it clear that the claimed element is used for a competitive type assay. In that regard, attention is directed to page 15 first full paragraph of the specification, where it is taught that a detection complex composed of analyte and conjugates 1 and 2 is formed from conjugate zone (2). The detection complex migrates through the capture zone (3) and reaches the detection zone (4) where for example a gold label serving as the label 2 is detectable by eye as a red coloration. When the sample contains no analyte, the conjugate mixture -- containing no analyte - is bound in the capture zone (3) and the visually detectable label 2 does not reach the detection zone (4). Hence, no coloration will be detectable there. As such, the detection zone in the element simply *does not* operate by having binding reagents for the analyte. As such, it is submitted that an artisan reading the instant specification would have gleaned therefrom the invention as now claimed.

Thus, the artisan would have understood that the detection zone devoid of a binding reagent was in the inventors' possession at the time of filing the instant application. Accordingly, it is submitted that the Examiner had no reasonable basis for challenging the disclosure as to support for the detection zone being devoid of a binding reagent.

Appellant respectfully contends that the claims of the present invention comply fully with the written description requirement of 35 U.S.C. 112, first paragraph. Reversal of the rejection based on that statutory section is requested.

Claims 15-26 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16-26 depend from claim 15.

The Examiner has asserted that claim 15 is confusing with respect to the recitation of a detection zone as it is unclear how the *detection* zone works.

The proper standard for determining definiteness under 35 U.S.C. 112, second paragraph, is whether a claim reasonably apprizes those of skill in the art of its scope. See *In re Warmerdam*, 33 F.3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994); *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.* 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). In order to determine whether a claim reasonably apprizes those skilled in the art of its scope, the meaning of the claims must be construed.

There is a heavy presumption in favor of ordinary meaning of the language of a claim. The Federal Circuit has identified two situations where a sufficient reason may exist to require entry of a definition of a claim term other than its ordinary and accustomed meaning. First, where a patentee or applicant has chosen to be his own lexicographer by setting forth a clear definition of a claim term. Secondly, where the terms of the claims are so deprive the claim of clarity that there is no means by which the scope of the claims may be ascertained from the language used. *Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 989, 50 USPQ 2d 1607, 1610 (Fed. Cir. 1999).

The Examiner takes issue with the use of the terminology “detection zone” as it appears in claim 15. The Examiner has stated that Appellant is attempting to redefine “detection” and “detection zone”. A review of Claim 15 as well as the specification as filed, demonstrates that Appellants were not acting as their own lexicographer, but rather clearly defined the “detection zone” in a manner that is consistent with its ordinary meaning.

Attention is first directed to Claim 15, which recites “a detection zone located downstream from the sample application zone and being the last zone of the element that allows liquid transport, the detection zone being devoid of a binding reagent that would enable detection of the analyte”. It is submitted that the terms “detection” and “detection zone” as used above are in accordance with their ordinary meaning that is well understood by ordinary practitioners in the field of analytical test devices.

In that regard, attention is directed to the specification, which defines the detection zone as being the region of the analytical element in which it is determined whether the examined analyte was present in the sample applied to the element (Page 7 lines 21-25). More specifically, the specification teaches that where for example a gold label serving as the detectable label is used and an analyte is present, the complex reaches the detection zone (4) where the gold label is detectable by eye as a red coloration (Page 15 lines 14-21). A further description of how such a label is detected is described in an Example (Page 25, Part F). That Example is specific to the point of including a color table correlating the intensity of the color with the analyte concentration. It is submitted that the specification and claims use the term “detection” in a manner consistent with their ordinary meaning.

As further evidence of the consistent usage of the term “detection”, attention is directed its dictionary meaning set forth in *WordNet*® 2.0, © 2003 Princeton University. Detection is defined as “the perception that something has occurred or some state exists”. This ordinary definition is entirely consistent with the descriptions of “detection” found in the specification as originally filed and recited in Claim 15.

Next, the Examiner further takes issue with the phrase “devoid of a binding reagent”. Specifically, The Examiner has asserted that the specification does not provide literal or implicit support with reasonable clarity for the phrase, and as such, the claimed element is considered to be new matter.

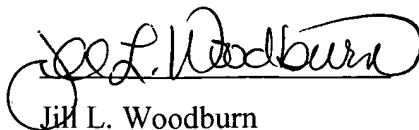
The specification certainly does provide implicit support for the phrase “devoid of a binding reagent” with reasonable clarity. As discussed above, support for a detection zone devoid of a binding reagent, is found in a specific example at Page 24, last paragraph. That Example describes a fleece Detection Zone (4) in detail, providing specifics on its composition as well as its absorptive capacity. The reference number (4) is included behind the term “Detection Zone” and is used to denote the Detection Zone in each of the Figures 1-4. It is of key importance to note that this specific example of the detection zone (4) lacks a binding reagent. As such, there is implicit support in both the text of the specification, and by reference in each of the Figures of a detection zone, devoid of a binding reagent.

Further, the specification makes it clear that the claimed element is used for a competitive type assay. In that regard, attention is again directed to page 15 first full paragraph of the specification, where it is taught that a detection complex composed of analyte and conjugates 1 and 2 is formed from conjugate zone (2). The detection complex migrates through the capture zone (3) and reaches the detection zone (4) where for example a gold label serving as the label 2 is detectable by eye as a red coloration. When the sample contains no analyte, the conjugate mixture – containing no analyte - is bound in the capture zone (3) and the visually detectable label 2 does not reach the detection zone (4). Hence, no coloration will be detectable there. As such, the detection zone in the element simply *does not* operate by having binding reagents for the analyte. Accordingly, Claim 15 reasonably apprizes those of skill in the art of its scope.

Reversal of the rejection of the claims under 35 USC 112, first and second paragraphs is requested.

Respectfully submitted,

Date: August 19, 2005



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APPENDIX OF CLAIMS IN APPEAL

Claims 1-14 (Cancelled).

Claim 15 (Previously presented): An element for the determination of an analyte in a liquid, the element comprising:

- a sample application zone,
- a detection zone located downstream from the sample application zone and being the last zone of the element that allows liquid transport, the detection zone being devoid of a binding reagent that would enable detection of the analyte;
- a zone containing immobilized analyte or analyte analogue located between the sample application zone and the detection zone,
- a material that enables liquid transport between the zones,
- a conjugate impregnated in a matrix material located upstream of the zone containing immobilized analyte or analyte analogue, the conjugate can be detached from the matrix material by liquid and comprises a first bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is a low molecular organic molecule, and
- a universal conjugate, located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a second bioaffine binding partner and a visually detectable label, the second bioaffine binding partner is capable of a specific binding reaction with the first detectable label, wherein the visually detectable label is a direct visually detectable label formed to carry out the determination of the analyte in the detection zone.

Claim 16 (Previously presented): The element as claimed in claim 15, wherein the first detectable label is digoxigenin or digoxin.

Claim 17 (Previously presented): The element as claimed in claim 16, wherein the second bioaffine binding partner is an antibody to digoxigenin or digoxin.

Claim 18 (Previously presented): The element as claimed in claim 16, further comprising an elution agent application zone located upstream of the sample application zone.

Claim 19 (Previously presented): The element as claimed in claim 18, wherein the impregnated conjugate and the universal conjugate are located between the elution agent application zone and the sample application zone.

Claim 20 (Previously presented): The element as claimed in claim 15, wherein the second bioaffine binding partner is an antibody to digoxigenin or digoxin.

Claim 21 (Previously presented): The element as claimed in claim 15, wherein the visually detectable label is metal particles or latex particles.

Claim 22 (Previously presented): The element as claimed in claim 21, wherein the visually detectable label is gold particles.

Claim 23 (Previously presented): The element as claimed in claim 15, wherein the impregnated conjugate and the universal conjugate are located in the sample application zone.

Claim 24 (Previously presented): The element as claimed in claim 15, further comprising an elution agent application zone located upstream of the sample application zone.

Claim 25 (Previously presented): The element as claimed in claim 24, wherein the impregnated conjugate and the universal conjugate are located between the elution agent application zone and the sample application zone.

Claim 26 (Previously presented): The element as claimed in claim 24, wherein the impregnated conjugate and the universal conjugate are located in the sample application zone.

Claims 27-42 (Cancelled).